

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **August 1, 2019**

GERON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

0-20859
(Commission File Number)

75-2287752
(IRS Employer
Identification No.)

149 COMMONWEALTH DRIVE, SUITE 2070
MENLO PARK, CALIFORNIA 94025
(Address of principal executive offices, including zip code)

(650) 473-7700
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

Geron Corporation (the "Company") is furnishing this information under Item 2.02 of Form 8-K.

The information in this Current Report, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. The information in this Current Report, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933, as amended, or the Exchange Act.

On August 1, 2019, the Company issued a press release announcing its financial results for the three and six months ended June 30, 2019. A copy of the press release is attached as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

| Exhibit No. | Description |
|----------------------|---|
| 99.1 | Press release dated August 1, 2019. |

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GERON CORPORATION

Date: August 1, 2019

By: /s/ Stephen N. Rosenfield

Name: Stephen N. Rosenfield

Title: Executive Vice President, Chief Legal
Officer and Corporate Secretary

Press Release Dated August 1, 2019

Geron Corporation Reports Second Quarter 2019 Financial Results and Recent Events

MENLO PARK, Calif., August 1, 2019 – Geron Corporation (Nasdaq: GERN) today reported financial results for the second quarter ended June 30, 2019, and recent events. The Company ended the second quarter with \$162.3 million in cash and marketable securities.

During the second quarter, data from the Phase 2 portion of IMerge was reported at the European Hematology Association (EHA) Annual Congress that further support Geron's late-stage development plans for the imetelstat program. Geron continues to plan to open the Phase 3 portion of IMerge in lower risk myelodysplastic syndromes (MDS) for screening and enrollment in August 2019.

"This past quarter, data presented at EHA for the Phase 2 portion of IMerge reported higher efficacy responses from prior reported data for both 8-week and 24-week RBC-TI rates, highlighting the meaningful and durable transfusion independence potentially achievable with imetelstat treatment in heavily transfusion dependent lower risk MDS patients. Accordingly, we're very much looking forward to the Phase 3 portion of IMerge opening for screening and enrollment later this month," said John A. Scarlett, M.D., Chairman and Chief Executive Officer. "In addition, a second EHA presentation reported results of statistical analyses in which the months of median overall survival were more than double for imetelstat-treated relapsed/refractory MF patients in IMbark, compared to real-world data from closely matched patients treated with best available therapy. This provides additional support for our ongoing strategic evaluation of potential late-stage development approaches and regulatory scenarios in relapsed/refractory MF as we prepare for an End of Phase 2 meeting with the FDA, which we're planning to conduct by the end of the first quarter of 2020."

Phase 3 Portion of IMerge Phase 2/3 Clinical Trial – Initial Site Initiations Complete and Trial to Open for Patient Screening and Enrollment in August 2019

In May, Geron completed the transfer of the imetelstat investigational new drug (IND) sponsorship from Janssen Biotech, Inc. (Janssen), and assumed complete development responsibility for imetelstat. Site initiations for the Phase 3 portion of IMerge were completed for several clinical sites in July 2019. Geron is planning for the trial to open for patient screening and enrollment later this month.

IMerge is a two-part Phase 2/3 clinical trial of imetelstat in transfusion dependent patients with lower risk MDS who are relapsed/refractory to erythroid stimulating agents (ESAs). The primary efficacy endpoint is the rate of red blood cell transfusion independence (RBC-TI) lasting at least eight weeks, or 8-week RBC-TI rate, which is defined as the proportion of patients achieving RBC-TI during any consecutive eight weeks since entry into the trial. Key secondary endpoints include the rate of RBC-TI lasting at least 24 weeks, or 24-week RBC-TI rate, durability of transfusion independence and the amount and relative change in RBC transfusions.

The Phase 3 portion of IMerge is designed as a randomized, double-blind, placebo-controlled clinical trial to test the hypothesis that imetelstat improves the rate of RBC-TI compared to placebo.

Approximately 170 patients are planned to be enrolled and randomized in a 2:1 ratio to receive either imetelstat or placebo. Many key aspects from the Phase 2 portion of IMerge remain the same for the Phase 3 portion. A target patient population of non-del(5q) lower risk MDS patients who were naïve to treatment with hypomethylating agents (HMAs) and lenalidomide was identified from the Phase 2 portion and will be enrolled in the Phase 3. In addition, the primary and secondary endpoints, the dose and schedule of imetelstat administration and many of the clinical sites remain the same as in the Phase 2. The Company is planning for the trial to be conducted at multiple medical centers globally, including North America, Europe, Middle East and Asia.

Second Quarter and Year-to-Date 2019 Results

For the second quarter of 2019, the Company reported a net loss of \$14.2 million, or \$0.08 per share, compared to \$6.9 million, or \$0.04 per share, for the comparable 2018 period. Net loss for the first six months of 2019 was \$24.3 million, or \$0.13 per share, compared to \$14.1 million, or \$0.08 per share, for the comparable 2018 period.

Revenues for the three and six months ended June 30, 2019 were \$101,000 and \$158,000, respectively, compared to \$208,000 and \$526,000 for the comparable 2018 periods. Revenues for the three and six months ended June 30, 2019 and 2018 included royalty and license fee revenues under various non-imetelstat license agreements. The decline in revenues reflects a reduction in the number of active research license agreements in 2019 related to the Company's human telomerase reverse transcriptase, or hTERT, technology as a result of patent expirations on the underlying technology.

Total operating expenses for the three and six months ended June 30, 2019 were \$15.3 million and \$26.7 million, respectively, compared to \$7.5 million and \$15.2 million for the comparable 2018 periods. Research and development expenses for the three and six months ended June 30, 2019 were \$10.1 million and \$16.0 million, respectively, compared to \$3.2 million and \$5.6 million for the comparable 2018 periods. The increase in research and development expenses, compared to the same periods in 2018, primarily reflects costs for the transition of the imetelstat program, including resuming sponsorship of the ongoing imetelstat clinical trials; expenses for start-up activities for the Phase 3 portion of IMerge; and higher personnel-related costs for the expanding development team. General and administrative expenses for the three and six months ended June 30, 2019 were \$5.2 million and \$10.6 million, respectively, compared to \$4.2 million and \$9.6 million for the comparable 2018 periods. The increase in general and administrative expenses, compared to the same periods in 2018, primarily reflects higher corporate and patent legal costs and increased personnel-related expenses for additional headcount to support the development organization.

Interest and other income for the three and six months ended June 30, 2019 was \$1.1 million and \$2.3 million, respectively, compared to \$717,000 and \$1.1 million for the comparable 2018 periods. The increase in interest and other income, compared to the same periods in 2018, primarily reflects higher yields on the Company's increased marketable securities portfolio.

The Company ended the second quarter of 2019 with \$162.3 million in cash and marketable securities. Since May 2019, the Company has raised cumulative net cash proceeds of approximately \$2.6 million from the sales of an aggregate of 1,893,091 shares of common stock under an At Market Issuance Sales Agreement, after deducting sales commissions and other offering expenses payable by Geron. The Company expects these net cash proceeds to provide additional financial flexibility as it advances the imetelstat development program. The funds will support future development costs, including conducting the Phase 3 portion of IMerge.

2019 Financial Guidance Reaffirmed

For fiscal year 2019, the Company expects total operating expenses to range from \$80 to \$85 million, of which approximately \$20 to \$25 million represents one-time costs that include imetelstat program transition activities from Janssen to Geron and purchase of drug product, drug substance and raw materials from Janssen to supply the Phase 3 portion of IMerge and prepare for new drug manufacturing. The Company continues to expect transition of the imetelstat program from Janssen to be completed by the end of the third quarter of 2019.

As of July 31, 2019, the Company had 38 employees, and plans to grow to a total of approximately 45 to 50 employees by year-end 2019, of whom half will be research and development personnel.

Conference Call

Geron will host a conference call to discuss second quarter and year-to-date financial results and recent events at 4:30 p.m. ET on Thursday, August 1, 2019.

Participants may access the conference call live via telephone by dialing domestically +1 (877) 303-9139 or internationally +1 (760) 536-5195. The conference ID is 2379646. A live, listen-only webcast will also be available on the Company's website at www.geron.com/investors/events. If you are unable to listen to the live call, an archived webcast will be available on the Company's website for 30 days.

About Imetelstat

Imetelstat is a novel, first-in-class telomerase inhibitor exclusively owned by Geron and being developed in hematologic myeloid malignancies. Early clinical data suggest imetelstat may have disease-modifying activity through the suppression of malignant progenitor cell clone proliferation, which allows potential recovery of normal hematopoiesis. Ongoing clinical studies of imetelstat consist of IMerge, a Phase 2/3 trial in lower risk myelodysplastic syndromes (MDS) and IMbark, a Phase 2 trial in Intermediate-2 or High-risk myelofibrosis. Imetelstat has been granted Fast Track designation by the United States Food and Drug Administration for the treatment of patients with transfusion dependent anemia due to non-del(5q) lower risk MDS who are refractory or resistant to an erythroid stimulating agent.

About Geron

Geron is a late-stage clinical biopharmaceutical company focused on the development and potential commercialization of a first-in-class telomerase inhibitor, imetelstat, in hematologic myeloid malignancies. For more information about Geron, visit www.geron.com.

Use of Forward-Looking Statements

Except for the historical information contained herein, this press release contains forward-looking statements made pursuant to the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such statements, include, without limitation, those regarding: (i) that the Phase 3 portion of IMerge is planned to be open for patient screening and enrollment in August 2019; (ii) that meaningful and durable transfusion independence is potentially achievable with imetelstat treatment in heavily transfusion dependent lower risk MDS patients; (iii) that there will be an End of Phase 2 meeting with the FDA by the end of Q1 2020 regarding potential development of imetelstat for relapsed/refractory MF patients; (iv) that approximately 170 patients are planned to be enrolled in the Phase 3 portion of IMerge; (v) that the Company expects its 2019 operating expenses to be \$80 to \$85 million; (vi) that the Company expects transition of the imetelstat program from Janssen to be completed by the end of the third quarter of 2019; (vii) that the Company expects to grow to 45 to 50 employees by year-end 2019; (viii) that imetelstat may have disease-modifying activity; (ix) that imetelstat may potentially be commercialized; and (x) other statements that are not historical facts, constitute forward looking statements. These statements involve risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. These risks and uncertainties, include, without limitation, risks and uncertainties related to: (i) whether the Company overcomes all the clinical, safety, efficacy, technical, scientific, intellectual property, manufacturing and regulatory challenges to enable the opening of the Phase 3 portion of IMerge for screening and enrollment in August 2019 and to enable the eventual commercialization of imetelstat; (ii) whether regulatory authorities permit the further development and commercialization of imetelstat on a timely basis, or at all, without any clinical holds; (iii) whether imetelstat is demonstrated to be safe and efficacious in clinical trials; (iv) whether any future efficacy or safety results may cause the benefit-risk profile of imetelstat to become unacceptable; (v) whether the Company will be able to successfully retain and recruit key personnel to support its development plans; (vi) whether there are unexpected operating expenses or events that cause the \$80 to \$85 million 2019 financial guidance to be revised; (vii) whether the transition of the imetelstat program from Janssen occurs on a timely basis, or at all; (viii) whether imetelstat actually demonstrates disease-modifying activity in patients; (ix) whether the Company is able to prepare and submit materials to the FDA for an End of Phase 2 meeting on a timely basis, or at all; and (x) whether imetelstat has adequate patent protection and freedom to operate. Additional information on the above risks and uncertainties and additional risks, uncertainties and factors that could cause actual results to differ materially from those in the forward-looking statements are contained in Geron’s periodic reports filed with the Securities and Exchange Commission under the heading “Risk Factors,” including Geron’s quarterly report on Form 10-Q for the quarter ended June 30, 2019. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made, and the facts and assumptions underlying the forward-looking statements may change. Except as required by law, Geron disclaims any obligation to update these forward-looking statements to reflect future information, events or circumstances.

Financial table follows.

GERON CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(UNAUDITED)

| <i>(In thousands, except share and per share data)</i> | Three Months Ended June 30, | | Six Months Ended June 30, | |
|--|--------------------------------|-------------|------------------------------|-------------|
| | 2019 | 2018 | 2019 | 2018 |
| Revenues: | | | | |
| License fees and royalties | \$ 101 | \$ 208 | \$ 158 | \$ 526 |
| Operating expenses: | | | | |
| Research and development | 10,134 | 3,204 | 16,040 | 5,644 |
| General and administrative | 5,191 | 4,246 | 10,643 | 9,561 |
| Total operating expenses | 15,325 | 7,450 | 26,683 | 15,205 |
| Loss from operations | (15,224) | (7,242) | (26,525) | (14,679) |
| Interest and other income | 1,113 | 717 | 2,275 | 1,111 |
| Change in fair value of equity investment | (98) | (350) | — | (475) |
| Other expense | (30) | (59) | (48) | (77) |
| Net loss | \$ (14,239) | \$ (6,934) | \$ (24,298) | \$ (14,120) |
| Basic and diluted net loss per share: | | | | |
| Net loss per share | \$ (0.08) | \$ (0.04) | \$ (0.13) | \$ (0.08) |
| Shares used in computing net loss per share | 186,556,082 | 174,475,244 | 186,475,055 | 167,538,530 |

CONDENSED BALANCE SHEETS

| <i>(In thousands)</i> | June 30, 2019 | December 31, 2018 |
|--|------------------|----------------------|
| | (Unaudited) | (Note 1) |
| Current assets: | | |
| Cash, cash equivalents and restricted cash | \$ 17,980 | \$ 10,844 |
| Current marketable securities | 134,778 | 152,714 |
| Other current assets | 2,004 | 2,500 |
| Total current assets | 154,762 | 166,058 |
| Noncurrent marketable securities | 9,497 | 18,582 |
| Property and equipment, net | 100 | 59 |
| Other assets | 1,866 | 585 |
| | \$ 166,225 | \$ 185,284 |
| Current liabilities | \$ 9,181 | \$ 7,551 |
| Stockholders' equity | 157,044 | 177,733 |
| | \$ 166,225 | \$ 185,284 |

Note 1: Derived from audited financial statements included in the Company's annual report on Form 10-K for the year ended December 31, 2018.

CONTACT:

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